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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,215	12/19/2000	Qi Jia	UNI.15/D	7672

25871 7590 10/18/2002

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/18/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,215

Applicant(s)

Jia et al.

Examiner

Patricia Patten

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 20, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 16, 19, 22, 23, and 26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15, 16, 19, 22, 23, and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

RCE Practice

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 9/20/02 has been entered.

Claims 17, 21, 24 and 25 were canceled. Claims 13, 15-16, 19, 22-23 and 26 remain pending in the application. Amendments filed have deleted the term 'benzophenanthradine' from the choice of alkaloids, limiting the claims particularly to a method for isolating aporphine alkaloids. Applicants have further limited the method of claim 13 to include purification of the extract by various chromatographic methods. New claim 26 is drawn to wherein the extract is neutralized to a pH between 4.5 and 7.0.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claim Rejections - 35 USC § 102

The Rejections as set forth in the Final Office Action dated 5/21/02 remain standing with regard to pending claims 13, 15-16, 19, and 22-23 for the following reasons:

Applicants' principal arguments reside in the contention that aporphine alkaloids are structurally different from benzophenanthradine alkaloids such as laurifoline and liriodenine: "...the aporphine alkaloids of the current invention will not be precipitated by neutralization with basic solution as described for benzophenanthridine alkaloids..and phenanthrene alkaloids...absorption chromatography, such as alumina and silica gel chromatography can not be utilized to purify aporphine alkaloids due to irreversible absorption" (p.6, Arguments).

However, the contention that aporphine alkaloids cannot be precipitated with basic solution is argument by counsel which has not been clearly substantiated with evidence in the arguments or the Instant specification. With regard to the assertion that aporphine alkaloids will not elute from a silica gel column, Applicants are directed toward the Instant specification at page 14 which clearly states that the third fraction of the dichloromethane extract was "...purified by column chromatography (38 cm X 5.0 cm column, **silica gel**)" (emphasis added) which consequently eluted Liriodenine, *an aporphine alkaloid*. Thus, it appears that Applicants

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statements with regard to the chromatographic properties of aporphine alkaloids are contradictory and are therefore not convincing. Further, silica gel is a type of 'size exclusion' chromatography, although it does contain constituents on the gel which also provide for some 'adherence' effect. Thus, the methods as outlined in claims 13 and 15-16 were disclosed by Southard et al. Applicants contend that the method is different because it extracts aporphine alkaloids. However, the method steps are anticipated by Southard et al., and thus, if there is a difference in the method, *the differences do not appear in the claims*. It is deemed that since the methods are the same, the extract disclosed by Southard et al. must have inherently contained aporphine alkaloids.

It remains deemed that although the structure of aporphine alkaloids differ with respect to benzophenanthridine alkaloids or phenanthrene alkaloids, the properties of the solubilities of the compounds would be similar due to the similarities of phenolic groups. Morphine for example, has four phenolic groups, the same number of phenolics as aporphine alkaloids. Again, Applicants have only speculated that these alkaloids could not be purified via the use of similar extraction protocols, and have not provided convincing evidence of such.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Southard et al. (US 5,013,553). Claim 26 is drawn to wherein the extract is neutralized to a pH between 4.5 and 7.0.

The teachings of Southard et al. were discussed in previous Office Actions. To reiterate, Southard et al. taught that extract was dissolved in water. Southard et al. did not specifically state wherein the extract was neutralized to a pH between 4.5 and 7.0.

Because the basic extract was dissolved in water, the ordinary artisan would have recognized that the pH of the solution after dissolution would have been approximately 7 before prior to precipitation with the acid. Thus, one of ordinary skill in the art would have been motivated to have neutralized the extract to about a pH of 7 in order to move the pH of the extract out of the basic range before addition of an acid with a low pH as taught by Southard et al.

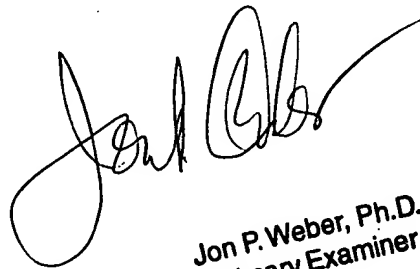
No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jon P. Weber", with a large, stylized flourish extending from the end of the signature.

Jon P. Weber, Ph.D.
Primary Examiner